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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DOWELL, PAUL THOMAS	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,150	CHIAUR ET AL.	
	Examiner	Art Unit	
	Paul Dowell	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 50-74 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 50-74 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 50-74 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 50-55, drawn to an isolated nucleic acid comprising a nucleotide sequence of SEQ ID NO:9, wherein said isolated nucleic acid encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:10; an isolated nucleic acid that hybridizes to the nucleotide sequence of SEQ ID NO:9; vectors comprising said isolated nucleic acids; and host cells comprising said vectors, classified in class 536, subclass 23.1.

II. Claim 56, drawn to a transgenic animal having cells which harbor a transgene, wherein said transgene comprises the nucleotide sequence of SEQ ID NO:9, classified in class 800, subclass 8.

III. Claim 57, drawn to an animal inactivated in a genetic locus, wherein said locus comprises the nucleotide sequence of SEQ ID NO:9, classified in class 800, subclass 8.

IV. Claim 58, drawn to an isolated polypeptide having the amino acid sequence of SEQ ID NO:10, classified in class 530, subclass 350.

V. Claim 59, drawn to an antibody that immunospecifically binds an isolated polypeptide having the amino acid sequence of SEQ ID NO:10, classified in class 424, subclass 130.1.

VI. Claim 60, drawn to a method of diagnosing proliferative and differentiative related disorders comprising measuring FBP5 gene expression in a patient sample, classified in class 435, subclass 4.

VII. Claims 61-69, drawn to a method for screening compounds useful for the treatment of proliferative and differentiative disorders comprising:

a) contacting a compound with a cell or cell extract, wherein said cell or cell extract is expressing/contains a polypeptide having the amino acid sequence of SEQ ID NO:10, or a fragment of said polypeptide, and its substrate(s) and

b) detecting a change in the activity of said polypeptide, classified in class 435, subclass 7.2.

VIII. Drawn to a method for treating a proliferative or differentiative disorder in a mammal comprising administering to the mammal a compound that modulates the expression of the FBP5 gene so that symptoms of the disorder are ameliorated, classified in class 514, subclass 44.

IX. Drawn to a method for treating a proliferative or differentiative disorder in a mammal comprising administering to the mammal a compound that modulates the activity of the FBP5 gene product (i.e. FBP5 protein) so that symptoms of the disorder are ameliorated, classified in class 514, subclass 44.

X. Drawn to a method for treating a proliferative or differentiative disorder in a mammal comprising administering to the mammal a compound that

modulates the expression of the FBP5 gene product (i.e. FBP5 encoding mRNA) so that symptoms of the disorder are ameliorated, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Groups I-V are directed to related inventions. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the products of groups I-V are structurally and functionally distinct. Group I is drawn to polynucleotides, vectors comprising said polynucleotides and host cells comprising said vectors; group II is drawn to a transgenic animal comprising an exogenously introduced transgene (i.e. a knock-in animal); group III is drawn to an animal comprising a disrupted genetic locus (i.e. a knock-out animal); group IV is drawn to a polypeptide; and group V is drawn to an antibody. Polynucleotides (vectors comprising said polynucleotides and host cells comprising said vectors), knock-in animals, knock-out animals, polypeptides and antibodies all possess distinct structure, function and utility each from the other. As such, the inventions of groups I-V do not overlap in scope, are not obvious variants and have materially different designs each from the other.

Groups VIII, IX and X are drawn to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive;

the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, groups VIII, IX and X are drawn to methods of treating a disorder comprising administering a compound to a mammal that: modulates the expression of an FBP5 gene (i.e. transcription of an FBP5 gene), modulates the activity of an FBP5 protein and modulates the expression of an FBP5 mRNA (i.e. translation of an FBP5 mRNA), respectively. The methods of groups VIII, IX and X are mutually exclusive and comprise unique steps that are not required for the other and as such have materially different design, mode of operation and effect.

Groups VI, VII are unrelated and groups VI, VII are unrelated each from groups VIII-X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, groups VI, VII are drawn to distinct methods with distinct methodological steps and intended goals. Further, groups VI, VII are drawn to methods with methodological steps and intended goals that are distinct each from groups VIII-X. The methods of groups VI, VII have different designs, modes of operation and effects from each other and, further, each from groups VIII-X.

Groups I-V are unrelated each to groups VI-X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant the products of groups I-V are not required for the methods of groups VI-X.

Because the inventions of groups I-X are distinct or unrelated for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter and will require separate and non-coextensive searches in the patent and non-patent literature, restriction for examination purposes as indicated is proper.

Linking Claims

Claims 70-74 link(s) inventions of groups VIII, IX and X. The restriction requirement amongst the linked inventions is subject to the nonallowance of the linking claim(s), claims 70-74. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C.

121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Election of Species

This application contains claims directed to the following patentably distinct species: a method for treating breast cancer, a method for treating ovarian cancer, a method for treating prostate cancer and a method for treating small cell lung carcinoma. The species are independent or distinct because the different types of cancers (i.e. breast, ovarian, prostate and small cell lung carcinoma) exhibit unique causes, symptoms and pathology and the methods of treating said cancers possess unique methodological steps (e.g. distinct tissues must be targeted).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 70 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1. 17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is (571)272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Dowell
Art Unit 1632

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER